K121929

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JAN 17 2013

2550 Decker Lake Blvd. Suite 26
Salt Lake City, Utah 84119

Section 5
510(k) Premarket Notification Summary
(As required by 21 CFR 807.92)

A. General Information

Date Prepared: December 19, 2012
Submitter's Name: Diacor Inc.
Address: 2550 Decker Lake Blvd. Suite 26, West Valley City, UT 84119
Telephone No: 801-467-0050 Fax: 801-487-3258
Contact Person: Tamara Tialavea

Establishment Registration Number: 1721113

Device Trade name: Diacor Zephyr "x-series" Patient Positioning and Transfer System

Device Common name: Patient Positioning and Transfer System

Device Classification name:
1. Accessory to Medical Charged-Particle Radiation Therapy System - 892.5050
2. Accessory Magnetic Resonance Diagnostic Device - 21 CFR 892.1000
3. Powered patient transfer device - 880.6775

B. Legally Marketed Predicate Devices

1. Patient Transfer Systems, Inc., AirPal Platform Powered Patient Transfer Device, Product Code FRZ, Regulation Number: 880.6775 (510(k) Exempt)
2. CIVCO MR & Radiological Patient Positioning Devices - K111340

C. Device Description

The Zephyr "x-series" Patient Positioning and Transfer System functions as an accessory to support a patient and positioning devices during imaging and radiation therapy procedures, and other procedures requiring the transfer of a patient. The Zephyr "x-series" Patient Positioning and Transfer System utilizes forced air as a low-friction bearing to transfer patients from one flat surface to another, eliminating the need to manually lift the patient.

D. Indications for Use/Intended Use

The Zephyr "x-series" Patient Positioning and Transfer System is indicated to aid in the support, positioning, and transfer of a patient for procedures involving imaging, including MRI, and external beam radiation therapy treatment with electrons, photons or protons, as well as other procedures requiring transfer of a patient.

E. Technological Characteristics

The Zephyr "x-series" Patient Positioning and Transfer System uses the same technology as the two predicate devices combined: 1) a patient positioning Kevlar base board (predicate CIVCO Kevlar base plate) and, 2) a low pressure air pad patient transfer system (predicate AirPal Patient Transfer); therefore, Diacor claims substantial equivalence.

F. Testing

Clinical Testing: N/A
Animal Testing: N/A
Bench Testing: Bench testing for attenuation, build-up, and MR safety was conducted. Attenuation measurements were taken using a Unidose-E electrometer with a Farmer Chamber FC65-G placed at a depth of 10cm in solid water. Measurements were made with and without the base board using both 6MV and 10MV clinical photon energies. The average attenuation factor measured 3.33, with a median of 2.65.

Build-up measurements were also taken using a Unidose-E electrometer with a PTW Advanced Markus Plane Parallel Chamber at various depths in solid water. Measurements were made with and without the base board. The results show that the materials and dimensions used in the board produce a dose buildup effect with an approximate equivalence to 6mm of tissue.

The Zephyr "x-series" Patient Positioning and Transfer System was tested for MR safety with a magnet and hand-held metal detector. The board was then positioned on the MR patient table and slid into the MR without any detectable pull by the magnet. The blower hose did show a slight attraction when directly next to the magnet. It was placed into the bore near the isocenter and was easily removed.

Conclusion: Based on our industry knowledge and experience, both attenuation and build-up test results were found to be in line with patient positioning devices that are readily found on the market. All components, excluding the air blower, tested MR Safe and are labeled accordingly.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Ms. Tami Tialavea
Chief Operations Officer
Diacor, Inc.
2550 Decker Lake Blvd., Suite 26
WEST VALLEY CITY UT 84119

January 17, 2013

Re: K121929
Trade/Device Name: Zephyr "X-series" Patient Positioning and Transfer System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: LNH, LHN, IYE, AND FRZ
Dated: November 14, 2012
Received: November 16, 2012

Dear Ms. Tialavea:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121929

Device Name: Zephyr "x-series" Patient Positioning and Transfer System

Indications for Use:

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Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health
510(k)_____**K121929**_____